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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/214,478	06/07/99	BRANTON	P 50013/002003

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1633	13

DATE MAILED: 01/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/214,478	Branton et al.
Examiner	**Group Art Unit**
Shin-Lin Chen	1633

☒ Responsive to communication(s) filed on *Nov 2, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-60 and 64-80* is/are pending in the applicat

Of the above, claim(s) *1-12, 14-16, 19-22, 24-26, 29-44, 55-60, and 64-80* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *13, 17, 18, 23, 27, 28, and 45-54* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

This application is a 371 of PCT/IB97/01041 and claims the benefits of provisional applications 60/021,273 filed 7-5-96 and 60/028,740 filed 10-22-96.

1. Applicant's election without traverse of group V, claims 13, 17, 18, 23, 27, 28 and 45-54, in Paper No. 12 is acknowledged.

2. Claims 1-12, 14-16, 19-22, 24-26, 29-44, 55-60 and 64-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

Priority

3. If applicant desires priority under 35 U.S.C. 119 (e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

Specification

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 13, 17, 18, 23, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MEP. § 2172.01. The omitted steps are: whether the transgene is expressed in the cell of a mammal and whether the expression of transgene(s) results in increase of apoptosis in said cell of said mammal.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 13, 17, 18, 23, 27, 28, 45-48 and 50-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 13, 17, 18, 23, 27 and 28 are directed to a method of increasing apoptosis in a mammal by using a transgene encoding any E4orf4 polypeptide or an apoptotic fragment thereof, or in combination with a second transgene encoding an E4orf6 polypeptide or an apoptotic fragment thereof. Claims 45-48 and 50-54 are directed to a pharmaceutical composition comprising a substantially pure nucleic acid encoding an E4orf4 polypeptide or a fragment of E4orf4 polypeptide, a nucleic acid having at least 50% identity or at least 75% identity to the sequence of SEQ ID No. 3, or a nucleic acid encoding E4orf4 having a conservative amino acid substitution relative to the E4orf4 sequence of SEQ ID No. 4.

The specification of the present application only discloses adenovirus nucleotide sequences SEQ ID Nos. 1 and 3 encoding E4orf6 (SEQ ID No. 2) and E4orf4 (SEQ ID No. 4) polypeptides, respectively. The claims encompass any E4orf4 or E4orf6 nucleotide sequence or fragment thereof derived from any adenovirus, any nucleotide sequence having at least 50% identity or at least 75% identity to the sequence of SEQ ID No. 3, and any nucleotide sequence encoding E4orf4 having a conservative amino acid substitution relative to SEQ ID No. 4.

Any E4orf4 or E4orf6 nucleotide sequence or fragment thereof derived from any adenovirus read on unrelated or unidentified gene which contains sequence that differs dramatically from the polynucleotide sequence of SEQ ID No. 1 or 3 as disclosed in the instant application. The claims encompass unrelated or unidentified nucleotide sequence at the 5' and 3' end or within the claimed nucleic acid sequence SEQ ID No. 1 or 3. The claims encompass variant structures of different polynucleotides, and in the present state of the art the structure of

one does not provide guidance to the structure of the others. The common attributes of any E4orf4 or E4orf6 nucleotide sequence or fragment thereof derived from any adenovirus are not described. The claims also encompass any mRNA that encodes any E4orf4 or E4orf6 polypeptide or fragment thereof, and thus include unknown and unidentified mRNA sequences from other genes.

Similarly, any nucleotide sequence having at least 50% identity or at least 75% identity to the sequence of SEQ ID No. 3 read on unrelated or unidentified gene which contains sequence that differs dramatically from the polynucleotide sequence of SEQ ID No. 3 as disclosed in the instant application. The claims encompass unrelated or unidentified nucleotide sequence at the 5' and 3' end or within the claimed nucleic acid sequence SEQ ID No. 3. The claims encompass variant structures of different polynucleotides, and in the present state of the art the structure of one does not provide guidance to the structure of the others. The common attributes of any nucleotide sequence having at least 50% identity or at least 75% identity to the sequence of SEQ ID No. 3 and still encoding a polypeptide with E4orf4 biological activity are not described. The claims also encompass any mRNA having at least 50% identity or at least 75% identity to the sequence of SEQ ID No: 3, and thus include unknown and unidentified mRNA sequences from other genes.

Any nucleotide sequence encoding E4orf4 having a conservative amino acid substitution relative to SEQ ID No. 4 reads on nucleotide sequences encoding a genus of structural variants of the amino acid sequence of SEQ ID No. 4. The specification of the present application fails to

specifically define what constitute a "conservative amino acid substitution". In view of the lack of such definition, the claims would read on nucleotide sequences encoding polypeptide sequence that differs drastically from SEQ ID No. 4. Thus, the claims encompass variant structures of different polynucleotides, and in the present state of the art the structure of one does not provide guidance to the structure of the others. The common attributes of any nucleotide sequence encoding E4orf4 having a conservative amino acid substitution relative to SEQ ID No. 4 are not described.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the disclosed nucleic acid sequences SEQ ID Nos. 1 and 3, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Thus, one of skill in the art would conclude that applicant was not in possession of the claimed polynucleotides because a description of only one member is not representative of the variants and is insufficient to support the claim.

9. Claims 13, 17, 18, 23, 27, 28 and 45-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for stimulating apoptosis *in vitro* by using a plasmid comprising nucleotide sequence of the disclosed SEQ ID No. 1 or 3 encoding E4orf6 or E4orf4, does not reasonably provide enablement for any pharmaceutical composition comprising a substantially pure nucleic acid encoding any E4orf4 polypeptide or a fragment of E4orf4 polypeptide derived from any adenovirus, a nucleic acid having at least 50% identity or at least 75% identity to the sequence of SEQ ID No. 3, or a nucleic acid encoding E4orf4 having a conservative amino acid substitution relative to the E4orf4, and a method of using a transgene

encoding any E4orf4 polypeptide or an apoptotic fragment thereof, or in combination with a second transgene encoding an E4orf6 polypeptide or an apoptotic fragment thereof to increase apoptosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 13, 17, 18, 23, 27 and 28 are directed to a method of increasing apoptosis in a mammal by using a transgene encoding any E4orf4 polypeptide or an apoptotic fragment thereof, or in combination with a second transgene encoding an E4orf6 polypeptide or an apoptotic fragment thereof. Claims 45-54 are directed to a pharmaceutical composition comprising a substantially pure nucleic acid encoding an E4orf4 polypeptide or a fragment of E4orf4 polypeptide, a nucleic acid having at least 50% identity or at least 75% identity to the sequence of SEQ ID No. 3, a nucleic acid encoding E4orf4 having a conservative amino acid substitution relative to the E4orf4 sequence of SEQ ID No. 4, or degenerate variants encoding the amino acid sequence of SEQ ID No. 4.

The specification of the present application only discloses stimulating apoptosis *in vitro* by using a plasmid comprising nucleotide sequence of the disclosed SEQ ID No. 1 or 3 encoding E4orf6 or E4orf4. The claims encompass using any nucleotide sequence encoding E4orf4 or E4orf6 or fragment thereof derived from any adenovirus, any nucleotide sequence having at least 50% identity or at least 75% identity to the sequence of SEQ ID No. 3, any nucleotide sequence encoding E4orf4 having a conservative amino acid substitution relative to SEQ ID No. 4, or

degenerate variants encoding the amino acid sequence of SEQ ID No. 4 to increase apoptosis or provide therapeutic effect for treating a particular disease or disorder of a subject *in vitro* or *in vivo*.

The term "pharmaceutical composition" implies production of therapeutic effect of said composition for a particular disease or disorder of a subject *in vitro* and *in vivo*. Therefore, the claims read on gene therapy using nucleic acid sequence set forth above for a particular disease or disorder *in vitro* or *in vivo*. The specification fails to provide adequate guidance and evidence for the correlation between the nucleotide sequence set forth above and the particular disease or disorder to be treated using said nucleotide sequence. The specification also fails to provide adequate guidance and evidence for the type of vector and promoter used, the administration routes of said vector, and whether introduction of the vector containing the nucleotide sequence set forth above into a subject including humans, mammals, insects, fishes etc. would provide sufficient expression of E4orf4 or E4orf6 or fragment thereof in the targeted cells such as to exhibit therapeutic effect for a particular disease or disorder of a subject *in vivo*.

The nature of the invention being gene therapy, the state of the prior art was not well developed and was highly unpredictable at the time of the invention. While progress has been made in recent years for gene transfer *in vivo*, vector targeting to desired tissues *in vivo* continues to be unpredictable and inefficient as supported by numerous teachings available in the art. For example, Miller (1995, FASEB J., Vol. 9, pages 190-199) review the types of vectors available for *in vivo* gene therapy, and conclude that "for the long-term success as well as the widespread

applicability of human gene therapy, there will have to be advances...targeting strategies outlined in this review, which are currently only at the experimental level, will have to be translated into components of safe and highly efficient delivery systems" (page 198, column 1). Deonarain (1998, Expert Opin. Ther. Pat., Vol. 8, pages 53-69) indicate that one of the biggest problems hampering successful gene therapy is the "ability to target a gene to a significant population of cells and express it at adequate levels for a long enough period of time" (page 53, first paragraph). Deonarain reviews new techniques under experimentation in the art which show promise but states that such techniques are even less efficient than viral gene delivery (see page 65, first paragraph under Conclusion section). Verma (Sept. 1997, Nature, Vol. 389, pages 239-242) reviews vectors known in the art for use in gene therapy and discusses problems associated with each type of vector. The teachings of Verma indicate a resolution to vector targeting has not been achieved in the art (see entire article). Verma also teaches appropriate regulatory elements may improve expression, but it is unpredictable what tissues such regulatory elements target (page 240, sentence bridging columns 2 and 3). Crystal (1995, Science, Vol. 270, page 404-410) also reviews various vectors known in the art and indicates that "among the design hurdles for all vectors are the need to increase the efficiency of gene transfer, to increase target specificity and to enable the transferred gene to be regulated" (page 409).

Further, Eck et al. (Pharmacological Basis of Therapeutics, 1996) indicates that the fate of the DNA vector itself (volume of distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up

by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced are all important factors for a successful gene therapy *in vivo*. These factors differ dramatically based on the vector used, the protein being produced, and the disease being treated (e.g. bridging pages 81-82). It is unclear whether introduction of the nucleotide sequence set forth above into a subject including humans, mammals, insects, fishes etc. would provide sufficient expression of E4orf4 or E4orf6 or fragment thereof in the targeted cells such as to exhibit therapeutic effect for a particular disease or disorder of a subject *in vivo*. One skilled in the art would not know how to use the nucleotide sequence set forth above for the treatment of a particular disease or disorder of a subject *in vivo*.

The specification of the present application fails to provide adequate guidance and evidence for a method of increasing apoptosis in a mammal by using a transgene encoding any E4orf4 polypeptide or an apoptotic fragment thereof, or in combination with a second transgene encoding an E4orf6 polypeptide or an apoptotic fragment thereof *in vivo*. The claims encompass any E4orf4 or E4orf6 polypeptide or fragment thereof derived from any adenovirus strain. The polypeptide sequence derived from different adenovirus strain could vary from each other and it is unclear whether those E4orf4 or E4orf6 polypeptide or fragment thereof still retain the function of increasing apoptosis as disclosed in the present application. The amino acid

sequence of a protein determines its structural and functional properties (including half-life), and predictability of any E4orf4 or E4orf6 polypeptide or fragment thereof which still retains the activity of increasing apoptosis *in vitro* or *in vivo* is extremely complex, and well outside the realm of routine experimentation, because accurate predictions of a protein's structure from mere sequence data are limited. Rudinger (Peptide Hormones, 1976) points out that "The significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study" (e.g. p. 6). Since a fragment of an E4orf4 or E4orf6 polypeptide could range from one amino acid to several amino acids, it would be unpredictable whether any fragment of an E4orf4 or E4orf6 polypeptide would still retain the activity of increasing apoptosis *in vitro* or *in vivo* within the targeted cells. One skilled in the art would not know how to use the full scope of the claimed E4orf4 or E4orf6 or fragment thereof to increase apoptosis in the targeted cells *in vitro* or *in vivo*.

Therefore, it is concluded that based upon the nature of the claimed invention, the state of the art, the unpredictability found in the art, the teaching and working examples provided, and the breadth of the claims that it would require a skilled artisan undue experimentation at the time of the invention to practice over the full scope of the invention claimed.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 47 and 49-52 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chroboczek et al, 4-8-1996.

Claims 47 and 49-52 are directed to a pharmaceutical composition comprising a substantially pure nucleic acid encoding a fragment of E4orf4 polypeptide, or a nucleic acid having at least 50% identity to the sequence of SEQ ID No. 3 or degenerate variants encoding the amino acid sequence of SEQ ID No. 4.

Chroboczek discloses a nucleotide sequence, GenEmbl Accession No. M73260, which is 100% identical to SEQ ID No. 3 (E4orf4), therefore, said nucleotide sequence would encode the amino acid sequence of SEQ ID No. 4 (E4orf4) or a fragment of E4orf4 polypeptide. The term "pharmaceutical" in the claims does not carry weight in the 102 rejection. Thus, claims 47 and 49-52 are clearly anticipated by Chroboczek.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 45, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohgi et al., 1991 (J. Biochem. Vol. 109, p. 776-785) in view of Chrobozek, 4-8-1996.

Claims 45, 53 and 54 are directed to a pharmaceutical composition comprising a substantially pure nucleic acid encoding an E4orf4 polypeptide and a pharmaceutically acceptable carrier. Claims 53 and 54 specify the nucleic acid is operatively linked to a promoter, such as a constitutive promoter or cell-type specific promoter.

Ohgi teaches preparation of a composition containing a vector comprising RNaseRh cDNA, transfection of yeast host cells with said vector, and purification of the recombinant RNaseRh protein from said yeast host cells (e.g. p. 777). The term "pharmaceutical" in the claims does not carry weight in the 103 rejection. Ohgi does not teach the presence of nucleotide sequence SEQ ID No. 3 encoding E4orf4 polypeptide.

Chroboczek discloses a nucleotide sequence, GenEmbl Accession No. M73260, which is 100% identical to SEQ ID No. 3 (E4orf4), therefore, said nucleotide sequence would encode the amino acid sequence of SEQ ID No. 4 (E4orf4) polypeptide.

It would have been obvious for one ordinary skill at the time of the invention to substitute the RNaseRh cDNA with the nucleotide sequence taught by Chroboczek to construct a vector and a host cell containing said vector as taught by Ohgi.

One ordinary skill at the time the invention was made would have been motivated to do so in order to produce and purify the recombinant human NKX3.1 protein and to study the function of said protein.

14. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al., 1995 (The FASEB Journal, Vol. 9, p.190-199) in view of Chrobozek, 4-8-1996 and Marcellus et al. (Sept. 1996, Journal of Virology, p. 6207-6215, IDS-ref).

Claim 48 is directed to a pharmaceutical composition comprising a substantially pure nucleic acid encoding an E4orf4 polypeptide in a viral vector and a pharmaceutically acceptable carrier.

Miller teaches construction of molecular conjugate vectors containing a plasmid DNA coupled to a ligand with cell or tissue affinity, retroviral, or adenoviral vectors comprising a therapeutic gene under the control of a cellular promoter, such as a tissue-specific regulatory element, and use of said vectors for gene delivery of said therapeutic gene to targeted cells for the

expression of said gene and treatment of a disease in a subject (e.g. p. 190, 192, 194, 195). Miller does not teach the presence of nucleotide sequence SEQ ID No. 3 encoding E4orf4 polypeptide.

Chroboczek discloses a nucleotide sequence, GenEmbl Accession No. M73260, which is 100% identical to SEQ ID No. 3 (E4orf4), therefore, said nucleotide sequence would encode the amino acid sequence of SEQ ID No. 4 (E4orf4) polypeptide.

Marcellus teaches an E4 product of adenovirus type 5 early region 4 is responsible for E1A-induced p53-independent apoptosis (e.g. abstract).

It would have been obvious for one of ordinary skill at the time of the invention to substitute the therapeutic gene as taught by Miller with the nucleotide sequence as taught by Chroboczek in order to deliver said nucleotide sequence to a targeted cell for the expression of E4orf4 polypeptide and to study the effect of E4orf4 polypeptide on E1A-induced p53-independent apoptosis.

It should be noted that provisional application 60/021,273 filed 7-5-96 only discloses that expression E4orf6 polypeptide could induce apoptosis of a cell but fails to support the apoptosis stimulating activity of E4orf4 polypeptide. Therefore, the priority date for the apoptosis stimulating activity of E4orf4 polypeptide is 10-22-96 of provisional application 60/028,740.

15. The information disclosure statement filed 8-13-99 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that

portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The reference U.S.S.N. 09/351,602 cited in form 1449-IDS is not considered because no legible copy of such reference has been provided.

Oath/Declaration

16. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

There is no signature of the inventor Josee N Lavoie,

Conclusion

No claims is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Karen M. Hauda

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Shin-Lin Chen, Ph.D.